AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions of claims in the application.

1. (Currently Amended) A solid dosage form in the form of a lyophilized wafer comprising:

(a) at least one active agent having an effective average particle size of ~~greater~~ less than ~~about~~ 2 microns prior to inclusion in the ~~dosage form~~ lyophilized wafer; ~~and~~

(b) at least one surface stabilizer adsorbed on the surface of the active agent; and

(c) pullulan having a concentration of about 99.9% to about 0.1% (w/w);

wherein:

(i) the ~~solid dosage form~~ lyophilized wafer has a friability of less than about 1%,

(ii) upon reconstitution, the active agent redisperses to the particle size present prior to incorporation in the lyophilized wafer, and

(iii) upon contact with water, the lyophilized wafer disintegrate within 3.5 minutes.

2. (Previously Presented) The solid dosage form of claim 1, wherein the concentration of pullulan is selected from the group consisting of about 85% to about 1% (w/w), about 60% to about 5% (w/w), and about 30% to about 10% by weight based on the total weight of the dry composition.

3. (Original) The solid dosage form of claim 1 having a friability selected from the group consisting of less than about 1%, less than about 0.9%, less than about 0.8%, less than about 0.7%, less than about 0.6%, less than about 0.5%, less than about 0.4%, less than about 0.3%., and less than about 0.2%

4. (Original) The solid dosage form of claim 1, further comprising at least one pharmaceutically acceptable sugar.

5. (Original) The solid dosage form of claim 4, wherein said sugar is selected from the group consisting of sucrose, xylitol, lactose, mannitol, sorbitol, glucose, mannose, fructose, and trehalose.

6. (Original) The solid dosage form of claim 4, wherein the concentration of the one or more pharmaceutically acceptable sugars can vary from about 1% to about 99% (w/w), based on the total weight of the dry composition.

7. (Original) The solid dosage form of claim 1, further comprising at least one pharmaceutically acceptable plasticizer.

8. (Original) The solid dosage form of claim 7, wherein said plasticizer is glycerin, polyethylene glycol, propylene glycol, or sorbitol.

9. (Original) The solid dosage form of claim 7, wherein the concentration of the one or more pharmaceutically acceptable plasticizers can vary from about 0.01% to about 70% (w/w), based on the total weight of the dry composition.

10. (Original) The solid dosage form of claim 1 further comprising at least one effervescent agent.

11. (Original) The solid dosage form of claim 1 comprising one or more pharmaceutically acceptable excipients.

12. (Cancelled)

13. (Currently Amended) The solid dosage form of claim 1, wherein said dosage form is selected from the group consisting of controlled release formulations, and fast melt formulations~~, aerosol formulations, lyophilized formulations, tablets, solid lozenges, capsules, and powders~~.

14. (Currently Amended) The solid dosage form of claim 13, wherein said dosage form is a fast melt dosage form which ~~substantially~~ completely disintegrates or dissolves upon contact with ~~saliva~~ water in a time period selected from the group consisting of ~~less than about 4 minutes, less than about 3.5 minutes,~~ less than about 3 minutes, less than about 2.5 minutes, less than about 2 minutes, less than about 90 seconds, less than about 60 seconds, less than about 45 seconds, less than about 30 seconds, less than about 20 seconds, less than about 15 seconds, less than about 10 seconds, and less than about 5 seconds.

15. (Original) The solid dosage form of claim 1, wherein said active agent is water-soluble.

16. (Original) The solid dosage form of claim 1, wherein said active agent is poorly water-soluble.

17. (Original) The solid dosage form of claim 1, wherein said active agent has highly toxic and/or highly potent properties.

18.-19. (Cancelled)

20. (Currently Amended) The solid dosage form of claim [[19]] 1, wherein the effective average particle size of the active agent particles is selected from the group consisting of can be less than about 1900 nm, less than about 1800 nm, less than about 1700 nm, less than about 1600 nm, less than about 1500 nm, less than about 1400 nm, less than about 1300 nm, less than about 1200 nm, less than about 1100 nm, less than about 1000 nm, less than about 900 nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

21. (Cancelled)

22. (Original) The solid dosage form of claim 1, wherein the concentration of the at least one active agent is from about 99.9% to about 0.01% (w/w), by weight based on the total weight of the dry composition.

23. (Currently Amended) The solid dosage form of claim [[21]] 1, wherein the concentration of the at least one active agent is selected from the group consisting of from about 99.5% to about 0.001%, from about 95% to about 0.1%, and from about 90% to about 0.5%, by weight, based on the total combined weight of the at least one active agent and at least one surface stabilizer, not including other excipients.

24. (Currently Amended) The solid dosage form of claim [[21]] 1, wherein the concentration of the at least one surface stabilizer is selected from the group consisting from about 0.0001% to about 99.9%, from about 5% to about 90%, and from about 10% to about 70%, by weight, based on the total combined dry weight of the at least one active agent and at least one surface stabilizer, not including other excipients.

25. (Previously Presented) The solid dosage form of claim 1, wherein the poorly soluble active agent is in the form of crystalline particles, semi-crystalline particles, or amorphous particles.

26. (Original) The solid dosage form of claim 1, wherein the at least one active agent is selected from the group consisting of COX-2 inhibitors, anticancer agents, NSAIDS, proteins, peptides, nutraceuticals, anti-obesity agents, corticosteroids, elastase inhibitors, analgesics, anti-fungals, oncology therapies, anti-emetics, analgesics, cardiovascular agents, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, immunosuppressants, antithyroid agents, antiviral agents, anxiolytics, sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, cardiac inotropic agents, contrast media, cough suppressants, diagnostic

agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, sex hormones, anti-allergic agents, stimulants and anoretics, sympathomimetics, thyroid agents, vasodilators, xanthines, acne medication, alpha-hydroxy formulations, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, and respiratory illness therapies associated with acquired immune deficiency syndrome.

27. (Withdrawn) The solid dosage form of claim 26, wherein the nutraceutical is selected from the group consisting of dietary supplements, vitamins, minerals, herbs, healing foods that have medical or pharmaceutical effects on the body, folic acid, fatty acids, fruit and vegetable extracts, vitamin supplements, mineral supplements, phosphatidylserine, lipoic acid, melatonin, glucosamine/chondroitin, Aloe Vera, Guggul, glutamine, amino acids, green tea, lycopene, whole foods, food additives, herbs, phytonutrients, antioxidants, flavonoid constituents of fruits, evening primrose oil, flax seeds, fish and marine animal oils, and probiotics.

28. (Currently Amended) The solid dosage form of claim [[21]] 1, wherein the nanoparticulate active agent composition comprises at least two surface stabilizers.

29. (Currently Amended) The solid dosage form of claim [[21]] 1, wherein the at least one surface stabilizer is selected from the group consisting of a nonionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and an ionic surface stabilizer.

30. (Original) The solid dosage form of claim 29, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, stearic acid esters and salts, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol

emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hydroxypropyl methylcellulose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylmethyl-cellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers, poloxamines, a charged phospholipid, dimyristoyl phophatidyl glycerol, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, triblock copolymers of the structure: -(-PEO)--(-PBO-)--(-PEO-)-, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl β-D-glucopyranoside, n-decyl β-D-maltopyranoside, n-dodecyl β-D-glucopyranoside, n-dodecyl β-D-maltoside, heptanoyl-N-methylglucamide, n-heptyl-β-D-glucopyranoside, n-heptyl β-D-thioglucoside, n-hexyl β-D-glucopyranoside, nonanoyl-N-methylglucamide, n-noyl β-D-glucopyranoside, octanoyl-N-methylglucamide, n-octyl-β-D-glucopyranoside, octyl β-D-thioglucopyranoside, lysozyme, a PEG derivatized phospholipid, PEG derivatized cholesterol, a PEG derivatized cholesterol derivative, PEG derivatized vitamin A, PEG derivatized vitamin E, and random copolymers of vinyl acetate and vinyl pyrrolidone.

31. (Withdrawn) The solid dosage form of claim 29, wherein the at least one cationic surface stabilizer is selected from the group consisting of a polymer, a biopolymer, a polysaccharide, a cellulosic, an alginate, a nonpolymeric compound, and a phospholipid.

32. (Withdrawn) The solid dosage form of claim 29, wherein the at least one surface stabilizer is selected from the group consisting of cationic lipids, benzalkonium chloride, sulfonium compounds, phosphonium compounds, quarternary ammonium compounds, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut

trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride bromide, C_{12-15}dimethyl hydroxyethyl ammonium chloride, C_{12-15}dimethyl hydroxyethyl ammonium chloride bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)$_4$ ammonium chloride, lauryl dimethyl (ethenoxy)$_4$ ammonium bromide, N-alkyl (C_{12-18})dimethylbenzyl ammonium chloride, N-alkyl (C_{14-18})dimethyl-benzyl ammonium chloride, N-tetradecylidmethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C_{12-14}) dimethyl 1-napthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C_{12-14}) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C_{12} trimethyl ammonium bromides, C_{15} trimethyl ammonium bromides, C_{17} trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyldimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, POLYQUAT 10™, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, MIRAPOL™,

ALKAQUAT™, alkyl pyridinium salts; amines, amine salts, amine oxides, imide azolinium salts, protonated quaternary acrylamides, methylated quaternary polymers, cationic guar, polymethylmethacrylate trimethylammonium bromide, polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, hexadecyltrimethyl ammonium bromide, poly (2-methacryloxyethyltrimethylammonium bromide) (S1001), poly(N-vinylpyrrolidone/2-dimethylaminoethyl methacrylate) di methylsulphate quarternary (S1002), and poly(2-methylacryloxyamidopropyltrimethylammonium chloride) (S1004).

33. (Withdrawn) A method of preparing a solid dosage form having low friability comprising:

(a) combining (i) at least one active agent and (ii) pullulan; and

(b) forming a solid dosage form,

wherein the solid dosage form has a friability of less than about 1%.

34. (Withdrawn) The method of claim 33, comprising:

(a) forming a dispersion or solution of at least one active agent;

(b) forming a pullulan solution;

(c) combining the dispersion or solution of (a) with the solution of (b); and

(d) formulating the resultant liquid of step (c) into a solid dosage form utilizing a pharmaceutically acceptable method.

35. (Withdrawn) The method of claim 34, wherein step (d) comprising lyophilization.

36. (Withdrawn) The method of claim 34, wherein the active agent has highly toxic and/or highly potent properties.

37. (Currently Amended) A method of treating a subject in need comprising administering to the subject an effective amount of a pullulan-comprising solid dosage form in the form of a lyophilized wafer, wherein:

(a) the ~~solid dosage form~~ lyophilized wafer comprises: (i) at least one active agent having an effective average particle size of ~~greater~~ less than ~~about~~ 2 microns prior to inclusion in the ~~dosage form~~ lyophilized wafer, (ii) at least one surface stabilizer adsorbed on the surface of the active agent, and (iii) pullulan having a concentration of about 99.9% to about 0.1% (w/w); ~~and~~

(b) the ~~solid dosage form~~ lyophilized wafer has a friability of less than about 1%,

(c) upon reconstitution, the active agent redisperses to the particle size present prior to incorporation in the lyophilized wafer, and

(d) upon contact with water, the lyophilized wafer disintegrate within 3.5 minutes.

38.-57. (Cancelled)